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August 24, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Re: U.S. Utility Patent Application
Appl. No. 10/727,534; Filed: December 5, 2003
For: **Medical Device for Delivering a Therapeutic Substance and Method Therefor**
Inventors: **BERG et al.**
Our Ref: **P686 CON2 (1737.1540002)**

Sir:

Transmitted herewith for appropriate action are the following documents:

1. SKGF Cover Letter;
2. Information Disclosure Statement;
3. List of cited references on Form PTO-1449 (6 pages);
4. A copy of each non U.S. Patent reference cited on Form PTO-1449 (28 documents: AL1-AT1, AL2-AT2, AL3-AT3, AL4, AM4, AR4 and AS4); and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
August 24, 2004
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Teresa U. Medler
Attorney for Applicants
Registration No. 44,933

TUM/JKM:bac
Enclosures

261841_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

BERG *et al.*

Appl. No.: 10/727,534

Filed: December 5, 2003

For: **Medical Device for Delivering a
Therapeutic Substance and
Method Therefor**

Confirmation No.: 7333

Art Unit: 3763

Examiner: *To Be Assigned*

Atty. Docket: P686 CON2 (1737.1540002)

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents AL1-AT1, AL2-AT2, AL3-AT3, AL4, AM4, AR4 and AS4 are provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicants have checked the appropriate boxes below.

- ☐ 1. Statement under 37 C.F.R. 1.704(d). Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- ☒ 2. Filing under 37 C.F.R. § 1.97(b). This Information Disclosure Statement is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.
- ☐ 3. Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final

Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.

- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ c. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$_____ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 4. Filing under 37 C.F.R. § 1.97(d) This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Enclosed find our PTO-2038 Credit Card Payment Form in the amount of \$_____ in payment of the fee under 37 C.F.R. § 1.17(p); in addition:

- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 5. The document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.
- ☒ 6. A concise explanation of the relevance of the non-English language document appears below:

Document AO2, Swiss Patent Publication No. 646 916, is in the German language. An English language abstract of document AO2 is attached as document AS4.

- ☐ 7. Copies of the documents are submitted herewith.
- ☐ 8. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).
- ☒ 9. No copies of U.S. patents and patent application publications cited on the attached Form PTO-1449 are submitted in accordance with 1276 OG 55 because this application was filed after June 30, 2003.
- ☒ 10. It is expected that the examiner will review the prosecution and cited art in the parent application no. 09/769,423 in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Teresa U. Medler
Attorney for Applicants
Registration No. 44,933

Date: August 24, 2004

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
P686CON2 (1737.1540002)APPLICATION NO.
10/727,534

FIRST NAMED INVENTOR

Berg *et al.*FILING DATE
December 5, 2003ART UNIT
3763

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	3,105,492	10/01/1963	Jeckel			10/01/1958
	AB1	3,425,418	02/04/1969	Chvapil <i>et al.</i>			04/15/1964
	AC1	3,451,996	06/24/1969	Sumyk <i>et al.</i>			02/12/1968
	AD1	3,523,807	08/11/1970	Gerendas			11/25/1966
	AE1	3,549,409	12/22/1970	Dyck			04/28/1969
	AF1	3,688,317	09/05/1972	Kurtz			08/25/1970
	AG1	4,118,449	10/03/1978	Rinde			12/09/1976
	AH1	4,188,188	02/12/1980	Willner <i>et al.</i>			09/27/1978
	AI1	4,229,540	10/21/1980	Coan			07/02/1979
	AJ1	4,229,838	10/28/1980	Mano			07/03/1978
	AK1	4,321,711	03/30/1982	Mano			10/12/1979

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	EP 0 366 564 A2	05/02/1990	Europe			Yes No
	AM1	WO 86/06729	11/20/1986	WIPO			Yes No
	AN1	WO 89/07932	09/08/1989	WIPO			Yes No
	AO1	WO 91/12779	09/05/1991	WIPO			Yes No
	AP1	WO 94/17108	08/04/1994	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	"Photolink™ Surface Modifications Technical Bulletin: Heparin Coatings For Medical Devices," Brochure from BSI Surface Modification Sciences, 4 pages, BSI Corporation (1994).
AS	1	Dyck, M.F., "Inorganic Heparin Complexes for the Preparation of Nonthrombogenic Surfaces," <i>J. Biomed. Mater. Res.</i> 6:115-141, John Wiley & Sons. (1972).
AT	1	Fischell, T.A., <i>et al.</i> , "Low-Dose, β -Particle Emission From 'Stent' Wire Results in Complete, Localized Inhibition of Smooth Muscle Cell Proliferation," <i>Circulation</i> 90:2956-2963, American Heart Association (1994).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. P686CON2 (1737.1540002)	APPLICATION NO. 10/727,534
	FIRST NAMED INVENTOR Berg <i>et al.</i>	
	FILING DATE December 5, 2003	ART UNIT 3763

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	4,357,312	11/02/1982	Hsieh <i>et al.</i>			07/16/1981
	AB2	4,540,573	09/10/1985	Neurath <i>et al.</i>			07/14/1983
	AC2	4,548,736	10/22/1985	Müller <i>et al.</i>			08/29/1983
	AD2	4,612,337	09/16/1986	Fox, Jr. <i>et al.</i>			05/30/1985
	AE2	4,613,665	09/23/1986	Larm			02/08/1983
	AF2	4,623,539	11/18/1986	Tunc			03/25/1985
	AG2	4,680,177	07/14/1987	Gray <i>et al.</i>			01/03/1984
	AH2	4,733,665	03/29/1988	Palmaz			11/07/1985
	AI2	4,733,665 B1	01/11/1994	Palmaz			11/07/1985
	AJ2	4,768,507	09/06/1988	Fischell <i>et al.</i>			08/31/1987
	AK2	4,800,882	01/31/1989	Gianturco			03/13/1987

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 94/27612	12/08/1994	WIPO			Yes No
	AM2	WO 97/07973	03/06/1997	WIPO			Yes No
	AN2	WO 97/42911	11/20/1997	WIPO			Yes No
	AO2	CH 646 916 A5	06/28/1985	Switzerland			X Yes No
	AP2	EP 0 815 806 A2	01/07/1998	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Whang, K., <i>et al.</i> , "A novel method to fabricate bioabsorbable scaffolds," <i>Polymer</i> 36:837-842, Elsevier Science (1995).
	AS	2	Lincoff, A.M., <i>et al.</i> , "Intracoronary Stenting Compared With Conventional Therapy for Abrupt Vessel Closure Complicating Coronary Angioplasty: A Matched Case-Control Study," <i>J. Am. Coll. Cardiol.</i> 21:866-875, Elsevier Science (1993).
	AT	2	Liu, S.Q., and Kodama, M., "Porous polyurethane vascular prostheses with variable compliances," <i>J. Biomed. Mater. Res.</i> 26:1489-1502, John Wiley & Sons (1992).

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. P686CON2 (1737.1540002)	APPLICATION NO. 10/727,534
	FIRST NAMED INVENTOR Berg <i>et al.</i>	
	FILING DATE December 5, 2003	ART UNIT 3763

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	4,873,308	10/10/1989	Coury <i>et al.</i>			09/30/1988
	AB3	4,886,062	12/12/1989	Wiktor			10/19/1987
	AC3	4,995,893	02/26/1991	Jenkins <i>et al.</i>			06/22/1989
	AD3	5,010,063	04/23/1991	Piani <i>et al.</i>			05/26/1989
	AE3	5,039,529	08/13/1991	Bergendal <i>et al.</i>			01/27/1989
	AF3	5,041,100	08/20/1991	Rowland <i>et al.</i>			04/28/1989
	AG3	5,059,166	10/22/1991	Fischell <i>et al.</i>			12/11/1989
	AH3	5,061,276	10/29/1991	Tu <i>et al.</i>			12/19/1988
	AI3	5,104,860	04/14/1992	Piani <i>et al.</i>			01/09/1990
	AJ3	5,342,605	08/30/1994	Illig			04/26/1993
	AK3	5,352,434	10/04/1994	Illig <i>et al.</i>			08/09/1993

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	WO 91/17744	11/28/1991	WIPO			Yes No
	AM3	WO 95/03083	02/02/1995	WIPO			Yes No
	AN3	WO 95/10989	04/27/1995	WIPO			Yes No
	AO3	WO 96/32907	10/24/1996	WIPO			Yes No
	AP3	WO 97/10011	03/20/1997	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	3	McNair, A.M., "Using Hydrogel Polymers for Drug Delivery," <i>Medical Device Technology</i> 7:16-18, 20 and 22, Advanstar (December 1996).
AS	3	van Beusekom, H.M.M., <i>et al.</i> , "Synthetic polymers as an alternative to metal in stents? In vivo and mechanical behaviour of polyethylene-terephthalate," <i>Supp. Circulation</i> 86:I-731, abs. no. 2912, American Heart Association (1992).
AT	3	Waksman, R., <i>et al.</i> , "Endovascular Low-Dose Irradiation Inhibits Neointima Formation After Coronary Artery Balloon Injury in Swine," <i>Circulation</i> 91:1533-1539, American Heart Association (1995).

EXAMINER

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. P686CON2 (1737.1540002)	APPLICATION NO. 10/727,534
	FIRST NAMED INVENTOR Berg <i>et al.</i>	
	FILING DATE December 5, 2003	ART UNIT 3763

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA4	5,399,318	03/21/1995	Mancilla <i>et al.</i>			05/02/1994
	AB4	5,451,424	09/19/1995	Solomon <i>et al.</i>			11/24/1992
	AC4	5,464,650	11/07/1995	Berg <i>et al.</i>			04/26/1993
	AD4	5,510,077	04/23/1996	Dinh <i>et al.</i>			09/15/1994
	AE4	5,531,735	07/02/1996	Thompson			09/27/1994
	AF4	5,541,305	07/30/1996	Yokota <i>et al.</i>			03/29/1995
	AG4	5,554,182	09/10/1996	Dinh <i>et al.</i>			04/27/1995
	AH4	5,571,166	11/05/1996	Dinh <i>et al.</i>			09/15/1994
	AI4	5,591,227	01/07/1997	Dinh <i>et al.</i>			04/27/1995
	AJ4	5,599,352	02/04/1997	Dinh <i>et al.</i>			09/15/1994
	AK4	5,609,629	03/11/1997	Fearnott <i>et al.</i>			06/07/1995

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL4	WO 99/16386	04/08/1999	WIPO			Yes No
	AM4	GB 2 084 466 A	04/15/1982	United Kingdom			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Spotnitz, W.D., <i>et al.</i> , "Fibrin Glue from Stored Human Plasma. An inexpensive and Efficient Method for Local Blood Bank Preparation," <i>Am. Surg.</i> 53:460-462, Southeastern Surgical Congress (1987).
	AS	4	Dialog File 351, Accession No. 4185512, Derwent WPI English language abstract for CH 646 916, Derwent Information Ltd. (1985).
	AT		

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. P686CON2 (1737.1540002)	APPLICATION NO. 10/727,534
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA5	5,624,411	04/29/1997	Tuch			06/07/1995
	AB5	5,679,400	10/21/1997	Tuch			06/07/1995
	AC5	5,697,967	12/16/1997	Dinh <i>et al.</i>			04/27/1995
	AD5	5,716,981	02/10/1998	Hunter <i>et al.</i>			06/07/1995
	AE5	5,776,184	07/07/1998	Tuch			10/09/1996
	AF5	5,843,146	12/01/1998	Cross, Jr.			04/30/1997
	AG5	5,848,995	12/15/1998	Walder			04/09/1993
	AH5	6,013,099	01/11/2000	Dinh <i>et al.</i>			04/29/1998
	AI5	6,187,370 B1	02/13/2001	Dinh <i>et al.</i>			09/16/1999
	AJ5	6,203,536 B1	03/20/2001	Berg <i>et al.</i>			06/17/1997
	AK5	4,794,002	12/27/1988	Henis <i>et al.</i>			09/05/1986

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. P686CON2 (1737.1540002)	APPLICATION NO. 10/727,534
	FIRST NAMED INVENTOR Berg <i>et al.</i>	
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA6	5,330,500	07/19/1994	Song			06/15/1992
	AB6	5,534,288	07/09/1996	Gruskin <i>et al.</i>			02/16/1995
	AC6	5,820,918	10/13/1998	Ronan <i>et al.</i>			07/11/1996
	AD6	6,106,454	08/22/2000	Berg <i>et al.</i>			06/17/1997
	AE6	5,591,199	01/07/1997	Porter <i>et al.</i>			06/07/1995
	AF6	5,634,899	06/03/1997	Shapland <i>et al.</i>			01/04/1994
	AG6	5,634,946	06/03/1997	Slepian			06/07/1995
	AH6	5,702,682	12/30/1997	Thompson			12/01/1995
	AI6	5,769,884	06/23/1998	Solovay			06/27/1996
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

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